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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,792	08/12/2002	Dangshe Ma	60364A	1289
109	7590	06/08/2004	EXAMINER	
THE DOW CHEMICAL COMPANY INTELLECTUAL PROPERTY SECTION P. O. BOX 1967 MIDLAND, MI 48641-1967			HARTLEY, MICHAEL G	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 06/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,792	MA ET AL.	
	Examiner	Art Unit	
	Michael G. Hartley	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-20 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/20/2024</u> . | 6) <input type="checkbox"/> Other: _____. |

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13 and 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson (US 5,756,065) in view of either one of Griffiths (WO 99/30745) or Geerlings (US 5,246,691).

Wilson discloses radioactive metal complexes comprising a functionalized chelant compound having the formulae as shown 4 and 7-10 that are used as radiopharmaceuticals. These formulae directly encompass the formulae and compounds thereof as claimed. Note that in formula IV on column 7, R4 can be isothiocyanato and R3 can be a C1 alkoxy (methoxy), which would yield the chelate, MEO-DOTA-NCS in claim 5. Wilson exemplifies Bz-DOTA-NCS and related compounds (see column 25, example 46, etc.) and clearly teaches that the phenyl moiety may be substituted with methoxy as an equivalent, see column 7, which would yield the claimed species of claim 5. Wilson also discloses conjugates of the chelants with most of the same antibodies as claimed, i.e., anticancer antibodies, see column 25. Wilson discloses that the chelants form complexes with various radiometals as equivalents, to take advantage of a desired radioemission property, see column 3.

Wilson fails to specifically disclose the use of the radiometal, Ac-225, as claimed.

However, Ac-225 is well known in the art as being a useful radiometal for radiopharmaceuticals that are analogous to those of Wilson.

Griffiths discloses radiopharmaceuticals which use the same chelant compounds as claimed, e.g., DOTA analogs and teaches that Ac-225 is known to be a useful radiometal that may be used in an equivalent manner to the same radiometals specifically disclosed by Wilson (e.g., Sm-153, Ho-166, etc.), see abstract and page 14.

Geerlings teaches that Ac-225 is a preferred radiometal for antibody targeted radiopharmaceuticals because of its optimal half-life, availability and cytotoxic effect on tumors, see columns 2-3.

It would have been obvious to one of ordinary skill in the art to use Ac-225 as the radiometal in the chelants disclosed by Wilson because it is known in the art that Ac-225 is useful in analogous DOTA-chelant radiopharmaceuticals as an equivalent to the metals disclosed by Wilson, as shown by Griffiths and because Ac-225 is known to be a preferred radiometal for such antibody targeted radiopharmaceuticals (as disclosed by Wilson) because of Ac-225's optimal half-life, availability and cytotoxic effect on tumors, as shown by Geerlings.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson (US 5,756,065) in view of either one of Griffiths (WO 99/30745) or Geerlings (US 5,246,691), as applied to claims 1-13 and 15-20 above, and further in view of either one of Scheinberg (XP-002194098, PTO-1449) or Co (US 5,714,350).

Wilson discloses radioactive metal complexes comprising a functionalized chelant compound which are bound to various antitumor antibodies, as set forth above.

Wilson, as modified by Griffiths or Geerlings above, fails to specifically disclose the use of the anticancer antibody HuM195.

However, this antibody is well known in the art as being an anticancer antibody for targeting radiopharmaceuticals, as shown by Scheinberg and Co.

Scheinberg teaches that HuM195 specifically targets myeloid leukemia cells for radiotherapeutic treatment using an alpha emitter, see abstract.

Co teaches that radiolabeled HuM195 is known to be useful for treating AML to due its efficient binding to leukemia cells, see column 1.

It would have been obvious to one of ordinary skill in the art to further modify the chelants disclosed by Wilson to use HuM195 as the anticancer antibody because HuM195 is a well known

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antibody the provides the advantage of efficiently targeting radiopharmaceuticals to leukemia cells to treat AML, as shown by Scheinberg or Co.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 12, the recitation of "Num195" is unclear, since the meaning thereof is not recognized or defined by the specification. This appears to be a typo and should be "HuM195". Such a change will obviate this rejection.

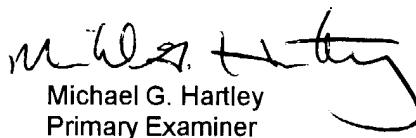
Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (571) 272-0616. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael G. Hartley
Primary Examiner
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